Invitation to Quote

Feasibility Report

On establishing a Digital Health Validation Lab
& Regulatory Sandbox (DHVRS) in Ireland

October 31st 2025

DHVRS is co-funded by the Government of Ireland and the European Union through the ERDF Southern, Eastern & Midland Regional Programme 2021-2027

1. Introduction

This Request for Quote (RFQ) is published to invite suitably qualified organisations to provide proposals for the completion of a **Feasibility Report on establishing a Digital Health Validation Lab & Regulatory Sandbox (DHVRS) in Ireland**.

The initiative is led by the Connected Health & Wellbeing Cluster (based at Dundalk Institute of Technology - DkIT), alongside a number of supporters, and is co-funded by *Government of Ireland and the European Union through the ERDF* fund via the Smart Regions funding at Enterprise Ireland. It is also co-funded by key partners including:

- **Tallaght University Hospital**
- **The HSE National Simulation Office**
- **dConnect Digital Health Innovation Hub**

Additional project supporters include EIT Health Ireland-UK, Amazon Web Services (AWS), the Regulated Software Research Centre at DkIT, Cyber Ireland, and the HSE Technology & Transformation unit.

There are two components of the DHVRS (see Figure 1); a **Digital Health Validation / Simulation Lab**, an immersive environment with medical staff and a replica of a health information system for co-design, testing, and validation; and a **Regulatory Sandbox**, a collaborative process where regulators evaluate the digital solutions in real-world settings, on a time-limited basis, at a small scale, and with appropriate safeguards in place – see Appendix 1 for additional details.

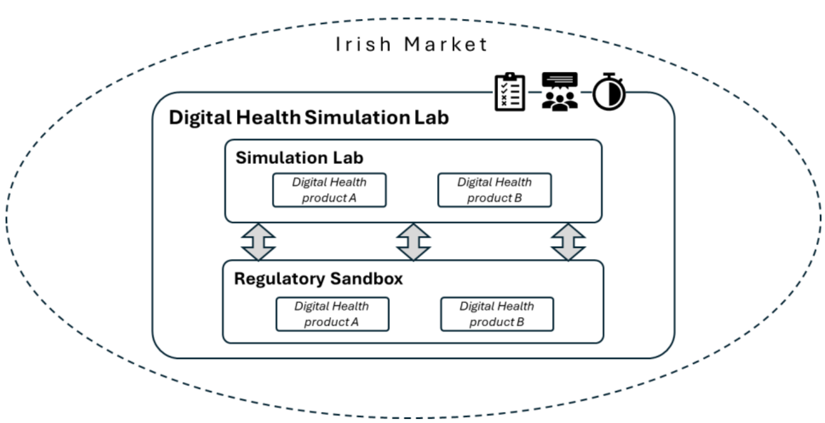

Figure 1. Components of the DHVRS: a Validation / Simulation Lab, and a Regulatory Sandbox.

2. Background of Tendering Organisation

Since its inception in 1970, Dundalk Institute of Technology (DkIT) has played a significant role in the development of the region. DkITs collaboration remit was augmented in 1989 developing the first campus-based enterprise and innovation centre in Ireland, the Regional Development Centre (RDC), to provide high growth trajectory businesses with supports to develop and grow their businesses, and to support commercialisation and industry collaboration with the research community at the institute. We work with many organisations; from student start-ups and academic spinouts to SMEs and multinational companies, and on a variety of projects. Since its inception, the RDC at DKIT has developed in excess of 320 Applied Research projects with industry, supported in excess of 2300 entrepreneurs through development programmes, and incubated over 230 companies. Digital Health is a strategic priority for DkIT, and we support the health ecosystem via the Connected Health & Wellbeing Cluster, the dConnect Digital Health Hub, and the DigiBio Innovators programme, alongside our specialised Research Centres.

The Connected Health & Wellbeing Cluster is hosted by Dundalk Institute of Technology (DkIT), and is co-funded by the Regional Technology Cluster Fund (Enterprise Ireland). Launched in November 2021, the Cluster has 80 members across the health ecosystem on the island of Ireland, with circa 75% based in industry. Members include large Tech and Pharma multinationals, start-ups, scale-ups, academia / R&D, healthcare providers, and innovation support agencies. The Cluster operates across six strategic pillars: innovation, collaboration, internationalisation, education and skills, regulation and interoperability, sustainable health tech, and personalised health monitoring (including sport tech and wearables). Members collaborate on joint R&D, upskilling, new product development, and accessing overseas markets.

See website for further information www.chwcluster.ie and www.dkit.ie .

3. Specification of Requirement

DkIT and partners invites proposals from suitably qualified and experienced practitioners to undertake and conduct a Feasibility Report into the establishment of a DHVRS in the Republic of Ireland (including the potential to include Northern Ireland). Working closely with the Cluster Manager, the designated company will be required to develop a final report to include:

- Horizon scanning and modelling that will involve conducting ***extensive research to map and compare existing models (Validation Labs & Regulatory Sandboxes),*** drawing on successful implementations in global hubs such as Melbourne, Glasgow, Singapore, and London.
  This analysis will distil best practices and strategic insights, enabling the development of a tailored approach that aligns with Ireland's unique healthcare landscape and regulatory environment, including International regulatory obligations. This will include objective examination of the strengths and weaknesses, opportunities and threats and key risks including constraints and external influences of the proposed DHVRS. It will also highlight International benchmark metrics that could be utilised for a potential DHVRS in the Republic of Ireland.
- The report will ***evaluate how such infrastructures can act as catalysts for growth in the Healthtech sector,*** facilitating faster time-to-market for new technologies and promoting standardisation across the industry. This includes understanding their impact on health technology development, acknowledging the time-limited nature of the sandbox, and foreseeing downstream activities like standardisation and health technology assessment. Key success metrics, such as the potential reduction in compliance lead times and associated costs, will be carefully assessed to quantify benefits.
- The scope of the feasibility Report includes ***examining the potential and practicalities of supporting an All-Island system where innovators would have access to testing on both the Republic of Ireland and Northern Ireland health systems,*** as a first step in achieving regulatory and technical compliance in global markets and healthcare systems.
- The Report will result in ***recommendations that outline potential budgets for creating and operating the DHVRS in Ireland.*** *This will include management operations for the regulatory sandbox & simulation lab, including potential fixed costs and operational costs.* The Feasibility Report will ***provide a clear timeline and costed timeframe to establish a DHVRS in the Republic of Ireland (with potential to also support Northern Ireland).*** The final report will include an overview of the financial feasibility and resourcing required to establish a DHVRS, and for its sustainability in the short, medium and long term. These should be aimed at informing healthcare innovation developers, health policy makers, economic support agencies, regulators, and other decision-makers. The feasibility report will outline potential **Health Validation Programmes** to support HealthTech Startups and Scale-ups by addressing practical barriers to innovation.

- This will include detailed implementation models, governance structures, and strategies for sustainable operation, ensuring the initiative's long-term viability and alignment with strategic health objectives in Ireland.
- An assessment of the ***potential economic impacts (short, medium, and long-term), including job creation for Ireland*** as a result of establishing a DHVRS.
- Assessment of the **cybersecurity requirements** for Digital Health Innovation that could be incorporated into the DHVRS, including regulatory requirements in Health, such as NIS2, Cyber Resilience Act etc. This would include an overview of the data protection requirements for Digital Health Innovation that could be incorporated into the DHVRS, including regulatory requirements such as GDPR.

<u>The proposal must include, but not limited to:</u>

- Detailed project plan for delivering the feasibility Report outlining the scope of work, including timelines.
- Stakeholder engagement mechanisms (e.g., oversight structure).
- Process and timelines for approval.
- Costings, including daily rates of personnel.

Submissions received without all sections above will be rejected. All proposed researchers and consultants put forward by your organization must demonstrate that they have the relevant experience in writing Feasibility Reports and have the appropriate knowledge of the health and innovation eco-system.

The budget should cover all research and analysis, delivery and expenses. Delivery is not expected to exceed €50,000 (VAT inclusive) in value, including all ancillary costs such as travel, meetings etc. Quotes in excess of this will not be considered.

Project Outline

The project timeline includes the following:

Project Phase	Timings	Outcomes / Actions
RFQ Published	October 31st	All queries should be sent to breanndan.casey@dkit.ie prior to November 21st.
Deadline for Submissions	November 28th 2025	No submissions will be accepted after November 28th
Evaluation of RFQ Submissions	w/c December 1st	Scoring of all submissions
Appointment of company	December 10th	Contract signed with timelines / outcomes
Mid-Contract Review	February 2026	Confirmation of Progress & Next steps
Final Review	March / April 2026	Completed Feasibility Report

4. Instructions to Tenderer

Proposals must be posted to address below, or submitted by email to breanndan.casey@dkit.ie, not **later than 5pm on Friday November 28th 2025**. Proposals received after this time will not be accepted. The email subject line must clearly note the RFQ Title as above. Responsibility for proof of delivery to the correct email address before the closing date rests with the tenderer. Failure to submit all the required information will lead to rejection of the RFQ.

If successful, the project lead, must be available for a face-to-face introductory meeting with DkIT and partners, a face-to-face or online mid-term review meeting, and present the key findings of the Report to the partnership consortium at the final stage.

DkIT reserves the right to:

- Reject any or all offers and discontinue this RFQ process without obligation or liability to any potential vendor
- Accept a submission other than the lowest priced offer
- Award a contract on the basis of initial offers received, without discussions or requests for best and final offers
- Award more than one contract
- Change or amend the timelines given above.

5. Criteria for Evaluation of Quotations

The contract will be awarded to the 'most economically advantageous' tender of those meeting the specifications set out based on the following award criteria. Quotes will be assessed according to the following scoring methodology:

Criteria	Marks awarded out of 10	Weightings	Weighted Score (1) x (2)
Understanding of the brief, and proposed methodology of the Feasibility Report	40	1	
Relevant expertise, experience and resources available	20	1	
Level of innovative approach and added value proposed	20	1	
Price [(1)]	20	1	

(1) **Price** - The most competitively priced tender will receive 20 marks; all other quotations will be receiving marks in relation to the most competitively priced i.e., highest scoring proposer quoted price / current proposer quoted price x max rating (i.e., 20).

If two bids are priced identically then the marks for the two appropriate ranking places will be added and divided by two with equal marks being awarded to each bid.

The contract will be awarded to the highest weighted score.

RFQ requirements:

The tender submission should:

- Outline the ***approach to be adopted, including methodology***, the skillsets, expertise and experience of key personnel and examples of previous similar assignments undertaken.
- Include *a* ***CV for the key personne****l* actively engaged on the project. It should also set out how an innovative approach will be adopted.
- Include a ***current Tax Clearance certificate***.
- Include any notification of any agreement or conflict of interest that may infringe on this contract.

The ownership of the completed Report and its contents will remain with Dundalk Institute of Technology. All costs of preparing a tender will be the responsibility of the tenderer.

Tenderers can submit hard copies via post, or a soft copy via email. Electronic copies should be submitted to breanndan.casey@dkit.ie

Hard copies to be delivered in a sealed envelope clearly marked:

"Feasibility Report: Digital Health Validation Lab & Regulatory Sandbox" For the attention of:

Breanndán Casey
Connected health & Wellbeing Cluster
Regional Development Centre
Dundalk Institute of Technology
Dublin Road,
Dundalk,
County Louth,

Ireland

A91 K584

Quotes must be submitted no later than **5pm on November 28th 2025**

6. Terms & Conditions

a. This Request for Quotation (RFQ) shall form part of the contract documents. The contract will not take effect until after unsuccessful proposers have been notified of the result of this tendering process.

b. The successful tenderer shall be responsible for the delivery of all services provided for within the contract based on a fixed price agreement set at the beginning of the contract. **Prices quoted in the tender cannot be increased during the contract period**. Payment for services covered by the proposed contract will be on foot of appropriate invoices, which will be based on agreed deliverables. Invoicing arrangements will be agreed with the successful proposer, following the award of contract.

c. **All costs (including travel & meetings) must be quoted in Euro inclusive of VAT**. DkIT retains the right to withhold payment where the successful tenderer has failed to meet his/her contractual obligations in the delivery of services to an acceptable level of quality.

d. Tenderers will be required to *provide evidence of employers and public liability insurance cover and any other insurance requirements* of DkIT

e. It will be a condition of appointment that the provider(s) selected will be able to produce for **inspection a valid Tax Clearance Certificate**.

f. In the event of a group of respondents jointly submitting an acceptable offer, the contract will be awarded to one contractor who acts as the agreed prime contractor. The prime contractor is responsible for the delivery of all services provided for under the terms of the contract and shall assume all the duties, responsibilities and costs associated with the position of prime contractor.

g. DkIT will not be liable in respect of any costs incurred by tenderers in the preparation of RFQ or any associated work effort.

h. Responses to this RFT will be evaluated in their own right. No recognition will be given to information previously submitted.

i. On successful completion of each phase, the report and all relevant documents / all completed material will be the property of DkIT.

j. Freedom of Information Act: DkIT will endeavor to hold confidential any information provided in this RFQ, subject to its obligations under law, including the Freedom of Information Act. Should the tenderer wish that any of the information supplied in this tender not be disclosed because of its sensitivity, the tenderer should, when providing the information, identify the sensitive information and specify the reason for its sensitivity. DkIT will consult with the tenderer about this sensitive information before making a decision on any Freedom of Information request received. If third parties request information pursuant to the Freedom of Information Act, unless this information has been identified as being sensitive, with supporting reasons, then it is likely to be released in response to a Freedom of Information request.

k. Conflicts-of-Interest: Any potential conflicts-of-interest involving a RFQ must be fully disclosed to DkIT. Failure to disclose a conflict-of-interest may disqualify a bidder or invalidate an award of contract, depending on when the conflict-of-interest comes to light.

l. DkIT will not be liable in respect of any costs incurred by consultants in the preparation of tenders, or any associated work effort.

7. Further Information and Query Handling

Every effort has been made to ensure that this RFQ contains all the necessary information for completion of tenders.

However, in the interests of equity for all tenderers, requests for additional information, clarification on the contents of this RFT and all other queries of substance (other than those relating to purely factual or procedural matters) **will be made available to all companies submitting proposals**. The deadline for submitting queries is Friday, November 21st.

Appendix 1: Overview & Background of a DHVRS

There are two components of the DHVRS (see Figure 1): a **Digital Health Validation / Simulation Lab**, an immersive environment with medical staff and a replica of a health information system for co-design, testing, and validation; and a **Regulatory Sandbox**, a collaborative process where regulators evaluate the digital solutions in real-world settings, on a time-limited basis, at a small scale, and with appropriate safeguards in place.

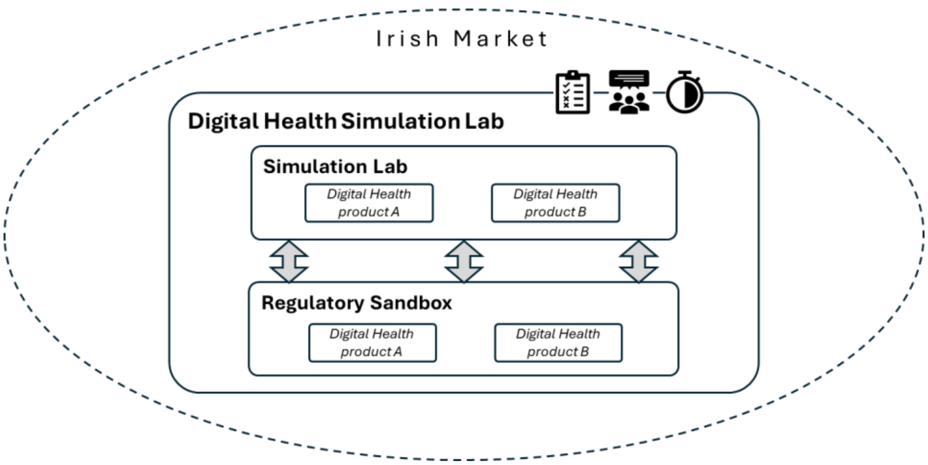

Figure 1. Components of the Digital Health Validation & Simulation Lab; a Simulation Lab and a Regulatory Sandbox.

A **Health Simulation Lab** is an environment designed to rigorously test digital health innovations, helping to mitigate risks and identify potential implementation barriers at an early stage. Simulation Labs, such as the Melbourne Validitron and the Digital Health Validation Lab in Glasgow, provide controlled settings where new health technologies can undergo thorough assessment before being deployed in real-world scenarios. This proactive approach supports efficient co-design, prototyping, and iterative testing, significantly reducing the time-to-market for new products [i]. *By addressing challenges before they escalate, health simulation labs play a crucial role in streamlining the innovation process and fostering safer, more effective health solutions,* having shown to reduce time-to-market, particularly for Healthtech Start-ups.

The Melbourne Validitron - "We help de-risk and accelerate digital health innovation, uncovering design issues and implementation blockers early enough to be fixed without wasting resources or *affecting patient care. We operate from state-of-the-art simulation-based research facilities within the Melbourne Connect innovation precinct. Our approach allows us to efficiently design, prototype and test digital health ideas before reaching the real world."*

Another component that is proposed to include in the DHVRS is a **Regulatory Sandbox** to provide a regulatory oversight layer with appropriate safeguards. Regulatory Sandboxes can be seen as temporary legal experimentations in a trail-and-error approach to oversight regulation, encouraging collaboration with actors (i.e., end users) to test new technologies in real-word environments for a limited time. This fosters a balance between safety and compliance while encouraging innovation, particularly in the digital sector. These controlled environments have been popular in the FinTech space to test new banking technologies and digital payment solutions. They are also used in the energy and utilities domains, set up to test new sustainable technologies and smart grid innovations without disrupting existing regulatory compliance. In Healthtech, Labs / Sandboxes can be used to test new medical devices, telemedicine solutions, or data-driven healthcare applications under the purview of health authorities.

The DHVRS is intended to facilitate the marketing of Digital Health solutions, which would require the participation of different stakeholders. Each partner brings a unique strength to the project, such as expertise in clinical practice, digital health infrastructure, regulatory oversight, and technological scalability. Establishing a DHVRS for physical immersion, including a replica of its health information system, would include an expectation to liaise with relevant external stakeholders for implementation, including:

- National regulatory bodies, such as HPRA (Health Products Regulatory Authority) and HIQA (Health Information and Quality Authority), national supervisory authorities, such as Data protection Commission (DPD), and the National Cyber Security Centre (NCSC), and standards organizations, such as NSAI, ISO, and IEC. This would make certain the DHVRS adherence to compliance and benchmark standards and will avoid potential duplication of activity.
- Healthcare providers, including hospitals, clinics, and medical professionals to contribute real-world clinical expertise for the DHVRS and test solutions in practical settings through for example the Health Innovation Hub Ireland (HIHI) and Health Service Executive (HSE).

- Academic and Research Centres, Universities, and Policy Think Tanks to aid in developing evidence-based approaches and exploring ethical dimensions.
- Health tech firms, AI developers, cybersecurity companies, and medical device manufacturers, ranging from large corporations to agile startups, to bring technical acumen and innovative solutions.
- IT infrastructure providers, such as AWS and IBM, to supply the technology backbone for the structure and data analysis of the DHVRS, creating a robust and collaborative environment to advance digital health innovation effectively.

The following **existing health examples** highlight the practical benefits and learning opportunities that Validation / Simulation Labs and Regulatory Sandboxes provide for both innovators and regulators:

- Singapore sandbox to test telemedicine.
- UK's MHRA AI-airlockMHRA AI-airlock is taking forward its new 'regulatory sandbox', the AI-Airlock, that will provide a regulator-monitored virtual area for developers to generate robust evidence for their advanced technologies. It is to assist in the development and deployment of software and AI medical devices.
- The Univeristy of Melbourne's Digital Health Validitron, a Simulation Lab and Digital Sandbox for Innovation validation. Prototypes can be tested in their Simulation Lab, an immersive physical space designed to test and improve its useability, acceptability, and safety. This space has digital components to replicate healthcare systems, which enables the workflow of Simulation Lab with healthcare professionals. - short video on above link or at https://youtu.be/la-9X9aiYGY.
- Massachusetts's e Health Institute's Digital Health Sandbox, providing a wide range of services supporting the lifecycle of validation and testing for digital health companies, including real world and simulated data sets, labs space, cybersecurity support, lab environments, and state-of-the-art equipment.
- Singapore Ministery of Health's Regulatory sandbox, a licensing experimentation and adaptation programme, supporting innovative healthcare service through regulatory sandboxes.

- FDA's Breakthrough Device ProgramFDA's Breakthrough Device Program, Introduced in 2012, the program is voluntary for certain medical devices and device-led combination products. This program is intended to provide patients and health care providers with timely access to medical devices by speeding up development, assessment, and review for regulatory approval. The program allows interaction with FDA experts to address topics and receive feedback.

Digital Health Validation Lab in UK provides access to blend expertise, resources, and strategic positioning to accelerate digital health innovation from concept or prototype to clinical adoption in an evidence-based approach.

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